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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

JOSHUA WILSON, et. al.,
Plaintiffs,
vs.
LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, et. al.,
Defendants.

Case No.: 4:22-cv-00438-ALM

AMICUS CURIAE BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Hon. Judge Amos L. Mazzant

COMES NOW, Pritish Vora, Amicus Curiae, ("Amicus"), by way of Pro Se, files with the Honorable Court his amicus curiae brief in the above referenced matter, and states as follows:

INTEREST OF THE AMICUS CURIAE

Amicus Curiae submits this informational brief in support of the Plaintiffs

JOSHUA WILSON, MICHAEL GROOTHOUSEN, RYAN MADIGAN, DERRICK GIBSON, STEVEN BROWN, BENJAMIN WALKER, SCOTT WELLS, BRITTANY PUCKETT, KARYN CHRISTEN, MICHAEL DOUGHTY, CARLEY GROSS, SUMMER FIELDS, JUSTIN KING, and THOMAS BLANKENSHIP, for themselves and all others similarly situated, and MEMBERS FOR THE ARMED FORCES FOR LIBERTY, an unincorporated association, (collectively, "Plaintiffs"), who are facing the order from the Secretary of the Department of Defense ("DoD") to become fully vaccinated with the experimental Covid-19 mRNA vaccine[1] or face disciplinary action. (Hereinafter for simplicity the order referred to as "the DoD mandate.").

Amicus provides information to this Court from publicly available sources found on the following sites, including, but not limited to, FDA.gov, CDC.gov, HRSA.gov, NIH.gov, and publicly available court filings on CourtListener.com via its RECAP archive, which are also available on PACER.gov, of relevant facts that warrant judicial notice,[2] and of facts that may escape the Court's consideration in determining the merits of the Plaintiffs' motion for preliminary injunction.

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[1] Amicus uses the word "vaccine" for convenience, but wholly rejects the notion of the Covid-19 injections being "vaccines." They are not. These are novel therapeutics using mRNA technology (e.g., Pfizer-BioNTech, Moderna) that do not use a live or attenuated virus to stimulate an immune response. They are considered "biological products" and/or "drugs." Also, J&J and Novavax are NOT approved.

[2] See Swindol v. Aurora Flight Sciences Corp., 805 F.3d 516, 519 (5th Cir. 2015).

This brief was not authored in whole or in part by counsel representing any party in this case. Amicus can observe objectively the pandemic that has grappled the nation and has transgressed into the Covid-19 vaccine mandate hysteria. Indeed, as Amicus types this brief, the country has now surpassed two full years of the pandemic and is on Day 860 of "15 days to slow the spread" announced on March 16, 2020. The "Covid is forever" will stop either through a Court ruling, or with mass non-compliance. Amicus has not received any monetary compensation to file this brief from any source, and does so at his own time, effort and expense.

Amicus shall focus on four distinct parts for the purpose of this brief and shall provide the Court with supporting references for each to warrant the granting of a preliminary injunction:

1. Defendants do not have "BLA compliant" lots of the Pfizer-BioNTech Covid-19 vaccine.

2. Defendants do not have Moderna's "FDA approved" Spikevax.

3. Defendants do not have Pfizer-BioNTech's "FDA approved" Comirnaty.

4. "DEATH" is a listed serious adverse event following administration of the Pfizer-BioNTech and Moderna Covid-19 vaccines, as stated in the emergency use authorization ("EUA") fact sheet for vaccine providers (i.e., the ones *administering* the vaccine). DEATH is **not** listed as a side effect in the EUA fact sheet provided **to recipients** (i.e., the ones actually *getting* the vaccine). (Emphasis added).

MEMORANDUM

The Court has authority to grant injunctive relief pursuant to the Federal Rules of Civil Procedure [F.R.Civ.P. 65] and review administrative decisions pursuant to the Administrative Procedures Act ("APA"). See Nevada v. U.S. Dept. of Labor, 218 F.Supp. 3d 520 (E.D. TX 2016). See also 5 U.S.C. § 702.[3] A movant is not required to prove its case in full at a preliminary injunction hearing. See Fed. Sav. & Loan Ins. Corp. v. Dixon, 835 F.2d 554, 558 (5th Cir. 1987).

As Amicus will show, the Plaintiffs are likely to succeed on the merits. See STAFFING, LLC, v. Quest Staffing Group, Inc., 335 F.Supp. 3d 856 (E.D. TX, 2018) (Mazzant, A.), (citing Halliburton Energy Serv. Inc., v. Axis Techs, LLC, 444 S.W. 3d 251, 260 (Tex. App. Dallas Aug. 21, 2014)). *"The purpose of the injunction is to remove the advantage created by the misappropriation."* See Halliburton, 444 S.W. 3d at 257. Here, the "misappropriation" by Defendants is what the Plaintiffs appropriately claim is the **bait-and-switch**, whereby the DoD is knowingly administering EUA-labeled vials and pawning them off "as if" they were licensed vaccines with full FDA approval and labeling, in complete violation of its own DoD mandate and of the Plaintiffs' statutory claims. (Emphasis added).

The Court has the ability to review APA claims. Counsel cited Darby v. Cisneros, 509 U.S. 137 (1993), which speaks for itself. (See PI motion at 7, n.12).

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[3] https://www.law.cornell.edu/uscode/text/5/702 (visited July 24, 2022)

F.R.Civ.P. 1, Scope and Purpose, states as follows: *"These rules govern the procedure in all civil actions and proceedings in the United States district courts, except as stated in Rule 81. They should be construed, administered and employed* ***by the court and by the parties*** *to secure the just, speedy, and inexpensive determination of every action and proceeding."* (Emphasis added).

F.R.Civ.P. 8(e) CONSTRUCTING PLEADINGS. *"Pleadings must be construed so as to do justice."*

F.R.Civ.P. 10(c) ADOPTION BY REFERENCE; EXHIBITS. *"A statement in a pleading may be adopted by reference elsewhere in the same pleading or in any other pleading or motion. A copy of a written instrument that is an exhibit to a pleading is part of the pleading for all purposes."*

F.R.Civ.P. 11(b) REPRESENTATIONS TO THE COURT. *"By presenting to the court, a pleading, a written motion, or other paper – whether by signing, filing, submitting, or later advocating it an attorney or unrepresented party certifies that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances."* F.R.Civ.P. 11(b)(3) states: *"****the factual contentions have evidentiary support*** *or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery."* (Emphasis added).

Failure to obey the rules mocks the system and destroys public confidence.

I. THE NON-EXISTENT "BLA COMPLIANT" LOTS

Amicus respectfully requests the Court to carefully examine the Declarations of Colonel Tonya Rans ("Rans Decl."), dated June 1st and July 10th, respectively. *"The DoD has received hundreds of thousands of Pfizer-BioNTech BLA-compliant, EUA-labeled COVID-19 vaccine doses and continues to use them."* (See Doc 14-2 at ¶ 19). *"In addition, the FDA determined that some lots of the vaccine produced at facilities and released in accordance with Pfizer-BioNTech's licensed Comirnaty vaccine were manufactured in compliance with the BLA." "As of May 20, 2022, DoD has 872 vials of BLA-compliant vaccine, equaling approximately 5,200 doses."* (See Doc 11-2 at ¶ 6 and ¶ 8).

The claims by the Rans Decl. regarding "BLA compliant" lots are complete poppycock. They were debunked by Plaintiffs' counsel, Mr. Brandon Johnson, and by Amicus. See Coker v Austin, No. 3:21-cv-01211-AW-HTC (N.D. Fla.).[4] ("Coker"). (Coker was prior named as "Doe #1-Doe #14 v. Austin).

To support their position, Defendants and the Rans Decl. relied upon the "Dear HCP" letter.[5] (See Doc 4, Exhibit 20, Boyce Letter, Notice to Healthcare Professionals) which referenced a list of the so-called "BLA approved" lots.[6] There were seven initial lots, with two additional lots added later.

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[4] https://www.courtlistener.com/docket/60630202/coker-v-austin/ (visited July 24, 2022)

[5] https://webfiles.pfizer.com/half-lot-number-letter-v3 (visited July 24, 2022)

[6] https://webfiles.pfizer.com/additional-lot-details-v3 (visited July 24, 2022)

The initial seven lot numbers are part of the factual record in Coker and identified as follows, with the corresponding manufacturing and expiration date:

Identified Lot Number	Manufacturing Date	Expiration Date
Lot Number FD7220	6/23/2021	11/30/2021
Lot Number FE3592	6/30/2021	2/28/2022
Lot Number FF2587	7/2/2021	3/31/2022
Lot Number FF2588	7/4/2021	3/31/2022
Lot Number FF2590	7/6/2021	3/31/2022
Lot Number FF2593	7/6/2021	3/31/2022
Lot Number FF8841	7/23/2021	3/31/2022

Amicus filed a brief in support of the Plaintiffs' Motion To Compel in Coker. (See Coker, Doc 99-1). In doing so, Amicus informed the Court that the lots were manufactured PRIOR to the approval of Comirnaty on August 23, 2021, and thus **"cannot be BLA compliant."** (Emphasis added). Judge Winsor had already opined in his prior ORDER dated November 12, 2021, in part: *"For starters, FDA licensure does not retroactively apply to vials shipped before BLA approval."* (See Coker, Doc 47 at 14). Indeed, any vial manufactured and/or shipped prior to August 23, 2021, would be an attempt to retroactively license an EUA vaccine, which was one of the main concerns advocated by Senator Ron Johnson. (See Coker, original Amicus Brief, Doc 66-1 at 5:16-24).

Not only were the lots manufactured *prior* to the Comirnaty approval, but also had their shelf life extended pursuant to the "Shelf-Life Extension Program" by FDA ("the SLEP").[7] According to the SLEP, the program is administered by DoD. The two additional lot numbers (FH8027 and FH8028) were manufactured on 9/3/2021 and 9/4/2021, respectively, and then extended pursuant to the SLEP.

In fact, all nine lots that Defendants promulgated in Coker (and are doing so *again* in THIS Court) were not "BLA-compliant." They are/were nothing more than the Pfizer-BioNTech EUA-labeled **experimental** Covid-19 inoculations that were authorized for emergency use, and thus pursuant to 21 U.S.C. § 360bbb-3, the Armed Forces had the option to REFUSE, period. (Emphasis added).

Defendants' strategy (whether intentional or not) in Coker by claiming the EUA-labeled "BLA compliant" lots of Pfizer-BioNTech "as if" it was Comirnaty was successful to mislead the Court in Coker to deny the preliminary injunction. However, now Defendants *here* omit a key phrase from Judge Winsor's ORDER. "*[If DoD is] administering Comirnaty...plaintiff's § 1107a issue disappears.*" (See Def. Opp. at 35). This is what the ORDER actually said: *"If the DoD is, in fact administering Comirnaty* ***(albeit EUA-labeled Comirnaty)****, the plaintiff's § 1107a issue disappears."* (See Coker, Doc 47 at 15). (Emphasis supplied). The factual

[7] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-dating-extension#covidvaccines (visited July 24, 2022)

record is further developed in Coker, and thus this Court may eventually conclude that Defendants' rehashed "BLA-compliant" lots claim violates F.R.Civ.P. 11.

II. THE NON-AVAILABILITY OF SPIKEVAX

Defendants attempted to find another "workaround" to their failed argument of "BLA compliant" lots of the Pfizer-BioNTech bait-and-switch. Defendants stated: *"On January 21, 2022, FDA approved the BLA for the SPIKEVAX COVID-19 mRNA vaccine, made by ModernaTX, Inc. Following subsequent FDA guidance, DoD issued a separate interchangeability memorandum for SPIKEVAX, consistent with the department's earlier interchangeability guidance for Comirnaty."* (See Doc 11-2, Rans Decl. at n.2). (See also Doc 14, Def. Opp. at 4).

Unfortunately for Defendants, their claim was based on the FDA press release and internal DoD "guidance documents" that carry no force of law. Defendants understood *prior* to making a filing in THIS Honorable Court that Spikevax is/was still **unavailable**. (Emphasis added).

Once again, Plaintiffs' counsel already addressed this issue, and so did Amicus. Indeed, Amicus filed a supplement informational brief in support of Plaintiffs in Coker, debunking Defendants' claim. (See Coker, Doc 84-1 at 4:5-24). Amicus already provided "DUE NOTICE" to Defendants that the CDC did not have any stored files for any FDA approved Covid-19 vaccines. (See Coker, Doc 66-1 at 11:1-9). CDC.gov updated its disclosure regarding Spikevax: *"The*

following SPIKEVAX products ***are not anticipated to be manufactured or orderable****...The NDCs related to the Carton of 10 7.5mL vials (80777-100-98/80777-100-15) will* ***not be manufactured****. Only the SPIKEVAX NDCs 80777-100-99 and 80777-100-11 will be manufactured at this time."* (Emphasis added).[8]

Neither the Armed Forces nor the general public has access to Spikevax, as no such product exists "at this time." Defendants made no offer to Plaintiffs for Spikevax because they cannot. Any person can search Vaccines.gov to find ALL Covid-19 vaccines by zip code. There is NO listing for Spikevax (or Comirnaty).[9]

III. THE UNAVAILABILITY OF "FDA APPROVED" COMIRNATY

According to the Rans Decl., *"On May 20, 2022 Pfizer-BioNTech's Comirnaty-labeled vaccine became available for ordering. To date, DoD has received over 42,000 doses within its supply chain and there are no restrictions to ordering this product."* (See Doc 14-2 at ¶ 19). Defendants claim to have made an offer (i.e., offer to contract) with the Plaintiffs. *"After this lawsuit was filed, the Armed Services, through undersigned counsel, offered to provide shots from a Comirnaty vial to any Plaintiff and to any member of the unincorporated association. But no individual accepted that offer."* (See Def. Opp. at 2).

Defendants fail to disclose if they have the actual **FDA APPROVED**

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[8] https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html (visited July 24, 2022)

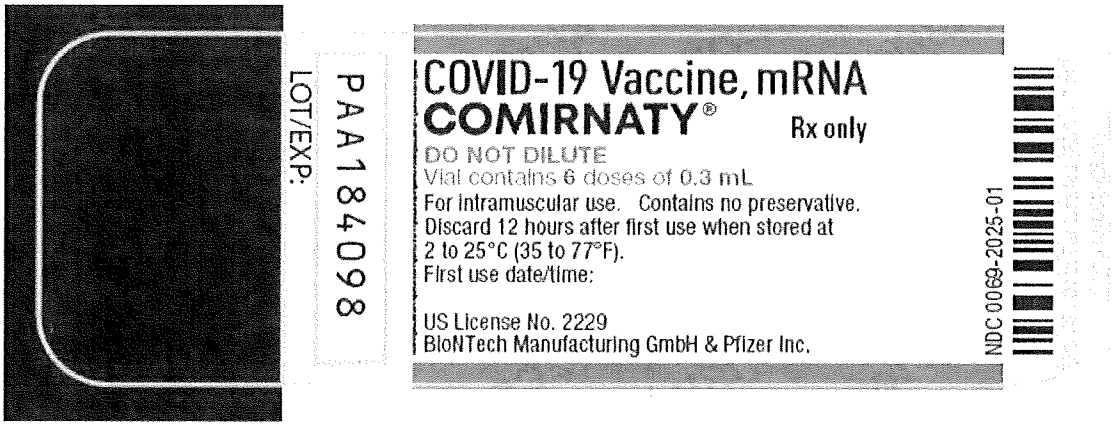
[9] https://www.vaccines.gov/search/ (visited July 24, 2022)

VERSION of Comirnaty, in accordance with proper structured product labeling. (Emphasis added). Comirnaty is, in fact, available, in EUROPE. The European Medicines Agency allows Comirnaty to be marketed throughout the European Union pursuant to a CMA (Conditional Marketing Approval), which is similar to an EUA (albeit for the Europeans). (See Coker, Doc 99-1 at 13:1-11).

The phrases "Comirnaty-labeled vial" and "Comirnaty-labeled vaccine" touted by Defendants' counsel are vague and ambiguous without any details regarding the manufacturing site, manufacturing date, and expiration of such alleged vials. NIH.gov depicts the vials of Comirnaty, showing the FDA approved version **must** contain a red watermark to verify its authenticity. (Emphasis added).

For the convenience of the Court, Amicus provides a screenshot below. The labeling information is publicly available at NIH.gov.[10]

COMIRNATY- covid-19 vaccine, mrna injection, suspension



[10] https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=48c86164-de07-4041-b9dc-f2b5744714e5 (visited July 24, 2022)

It is undisputed that NOBODY was getting Comirnaty in the entire United States when FDA issued the press release, or the day after when DoD initiated the DoD mandate on August 24, 2021, or anytime thereafter. In fact, CDC.gov still lists Comirnaty as "not orderable." Comirnaty does not appear in the National Vaccine Injury Compensation Program ("NVICP") for FDA approved vaccines.[11] Defendant HHS has not placed Comirnaty (or Spikevax) in the NVICP, as neither Pfizer nor Moderna has paid the .75 cents excise tax per dose to the U.S. Treasury (a mere pittance) to cover potential future compensation claims, despite 1,350,947 VAERS adverse reports through July 15, 2022. (See openvaers.com/covid-data).

IV. "DEATH" IS LISTED AS A SERIOUS ADVERSE EVENT

As Amicus has clearly stated in prior briefs in Federal Court, there are TWO separate EUA fact sheets regarding the Pfizer-BioNTech Covid-19 vaccines (also TWO for Moderna). One is for the recipients, and the other is for healthcare providers. Amicus spent four full pages in Coker explaining the variations of each, and the EUA facts sheets are a matter of public record. The one for healthcare providers lists "serious adverse events" including, but not limited to, "DEATH." (See Coker, Doc 66-1 at pages 15-18). See also Robert v. Austin, No. 1:21-cv-

[11] https://www.hrsa.gov/vaccine-compensation/covered-vaccines (visited July 24, 2022)

02228-RM-STV (Dist. Colo.),[12] (appeal filed, Case No. 22-1032, 10th Cir.). ("Robert"). The Amicus brief in Robert speaks for itself.

Amicus informs the Court what the Defendants fail to disclose: FDA licensed vaccines DO NOT come with EUA fact sheets. Instead, they come with Vaccine Information Statements ("VIS"). As Amicus explained in Robert (which the Court completely ignored), CDC.gov makes a clear distinction between an EUA fact sheet and a VIS. According to the CDC, *"There is no VIS for COVID-19 vaccines authorized under an EUA. Instead, the FDA-issued EUA Fact Sheet for Recipients and Caregivers for each Covid-19 vaccine must be used."* An EUA label on a vial of a Covid-19 vaccine means what it says and says what it means: **"For Emergency Use Authorization."** (Emphasis added).[13] Amicus respectfully requests the Court to fully consider *why* the Plaintiffs refused the offer to contract.

SUMMARY

Based on the foregoing, Plaintiffs have met the four factors to warrant the relief they seek regarding a preliminary injunction. Plaintiffs have a strong likelihood of success on the merits. There is threat of irreparable harm in the absence of preliminary relief. There is no hardship to the Defendants if the requested relief is granted. The public interest is served by an injunction. Indeed,

[12] https://storage.courtlistener.com/recap/gov.uscourts.cod.209086/gov.uscourts.cod.209086.42.1_1.pdf (last visited July 24, 2022).

[13] https://www.cdc.gov/vaccines/covid-19/eua/index.html (last visited July 24, 2022)

no reasonable person wants a member of the Armed Forces to suffer a discharge for refusing an experimental drug. There is no listing on the NVICP, so no recourse for damages, even for DEATH. Defendants possess EUA-labeled lots of the Covid-19 vaccines, which cannot be mandated by DoD. They do **not** have Spikevax, and the "availability" of Comirnaty is highly suspect. (Emphasis added).

The Declaration of Benjamin D. Walker, Maj. USAF ("Walker Decl."), states in part: *"There is a problem with commissioned United States Officers who do not speak up when they have a feeling that something is not right, who do not request due process, and who do not exercise their God-given ability to discern."* (See Doc 3-8, pg. 12, ¶ 20). ***"Every COVID-19 refusal within my personal knowledge has been recommended for separation, even when it has been shown that FDA approved vaccines do not exist and it is impossible for the member to comply with the order."*** (See Walker Decl. at ¶ 29). (Emphasis added). The entire declaration speaks for itself, and this is just one of many filed in Federal Court.

A Pro Se Plaintiff from the Northern District of Alabama once stated in his 11th Circuit petition for rehearing (en banc) in a FCRA claim, addressing the Court regarding the Federal Rules of Civil Procedure: *"Even the fictional character from the movie John Wick must follow certain protocols when entering The Continental. Why?* ***Because those are the rules.*** *(emphasis added)."* See Williams v. Capital One Bank (USA) N.A. et. al., Case No. 18-14143 (11th Cir. 2018).

CONCLUSION

Defendants decided to waltz their way into a Texas Federal Court with their continued *ipse dixit* claims of "BLA compliant" lots and "interchangeability" arguments. When repeated factual contentions lack evidentiary support, and face NO admonishment by the Courts, it undermines the credibility of the judiciary.

Simply stated, the repeated action by Defendants is akin to recidivist behavior. The salient fact remains: NO person is either administering or receiving a "BLA compliant" or "FDA approved" Covid-19 vaccine, as no such vaccine is/was **available** despite the recent magical arrival of the so-called vials of "Comirnaty." (Emphasis added). Defendants have no legitimate compelling interest to continue with their bait-and-switch. Thus, this case is perfectly ripe for an injunction.

WHEREFORE, Amicus respectfully requests that Plaintiffs' motion for preliminary injunction be GRANTED.

Respectfully submitted on this day of: July 27, 2022

By: Pritish Vora

Pritish Vora, Amicus Curiae, Pro Se

CERTIFICATE OF SERVICE

I, Pritish Vora, Amicus Curiae, hereby certify that I sent the Amicus Brief to the Clerk of the Court via FedEx on July 27, 2022, and a copy of same was sent via U.S. first class mail, postage prepaid, to each of the respective parties below.

Respectfully submitted by:

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